



Food and Drug Administration
Rockville MD 20857

Re: LIPOSORBER LA-15® System
Docket No. 96E-0189

AUG - 7 1996

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
U.S. Patent and Trademark Office
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

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DEPUTY ASSISTANT
COMMISSIONER FOR PATENTS

Dear Mr. Kunin:

This is in regard to the application for patent term extension for U.S. Patent No. 4,637,994 filed by Kanegafuchi Kagaku Kogyo Kabushiki Kaisha, under 35 U.S.C. § 156. The medical device claimed by the patent is LIPOSORBER LA-15® System, Premarket Approval Application (PMA) number 910018.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of this product under section 515(d) of the Federal Food, Drug, and Cosmetic Act.

The PMA was approved on February 21, 1996, which makes the submission of the patent term extension application on April 19, 1996, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Louis Gubinsky
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Washington, DC 20037-3202